

# The HPV Vaccine:

What Health Care Providers Need to Know

What are the Main Messages About Human Papillomavirus Vaccine (HPV)

## for Your Patients?

- » Preventing cancer is the most important benefit of HPV vaccine.
- » HPV vaccines are licensed for both males and females.
- » Three doses of HPV vaccine over six months are needed.
- » Routine Pap screening for cervical cancer remains important regardless of vaccination against HPV.
- » HPV vaccines are safe.

### What is HPV?

There are more than 100 different types of HPV; over 40 can infect genital skin or mucous membranes. HPV types are subdivided into high-risk types that can cause cancer and low-risk types that can cause warts. The vast majority of HPV infections are asymptomatic and resolve without ever causing disease, but persistent HPV infections can lead to cancer.<sup>1</sup>

### What cancers are related to HPV infections?

Infection with high-risk HPV causes almost all cases of cervical cancer. HPV types 16 and 18 account for about 70% of cervical cancers in the United States.<sup>2,3</sup> Even though Pap Screening can aid in early diagnosis, each year about 12,000 women in the United States are diagnosed with cervical cancer and more than 4,000 die from it. More than half of women with cervical cancer have not had a recent Pap test.<sup>4</sup>

HPV types 16 and 18 are associated with 60% of oropharyngeal cancer and 95% of anal cancer in both men and women. They also cause cancer of the vagina, vulva and penis. HPV infections are associated with about 12,000 cancers in men each year.<sup>5</sup>

### How is HPV Transmitted?

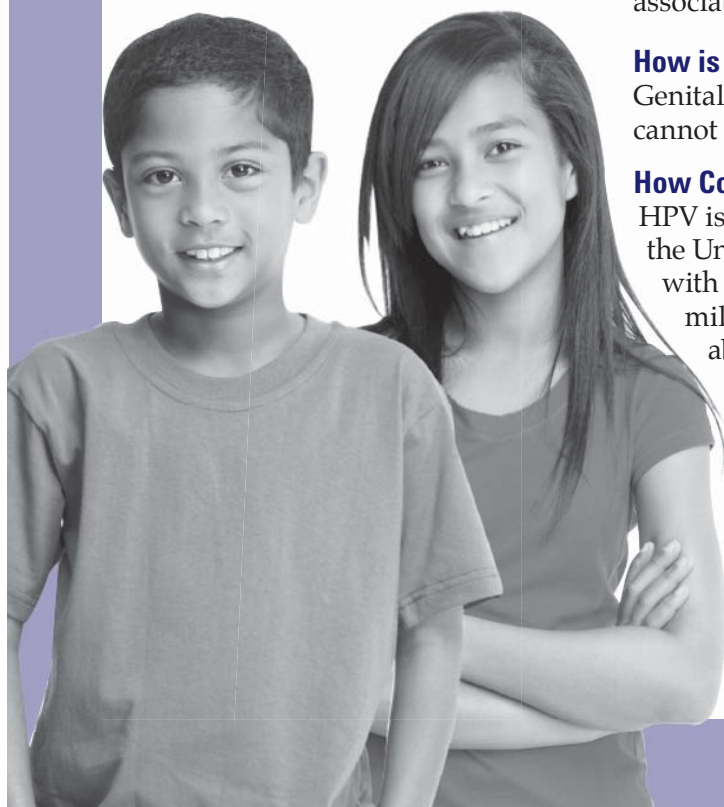
Genital HPV is transmitted sexually through genital contact and cannot be entirely prevented by condom use.

### How Common is HPV Infection?

HPV is among the most common sexually transmitted infections in the United States. Nearly all sexually active people will be infected with genital HPV at some point in their lives. An estimated 79 million men and women are currently infected, and there are about 14 million new infections each year.<sup>6</sup>

### How Many HPV Vaccines are There?

There are currently two HPV vaccines. Gardasil®, produced by Merck, is a quadrivalent vaccine against HPV types 6, 11, 16, and 18 and licensed for use in females and males ages 9 through 26 years.<sup>7</sup> Cervarix®, developed by GlaxoSmithKline, is a bivalent vaccine against HPV types 16 and 18 licensed for females ages 10 through 25 years. Neither vaccine contains the preservative thimerosal.<sup>8</sup>



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### How is HPV Vaccine Administered?

The HPV vaccines are given intramuscularly as a 0.5 mL dose in a three-dose series. The second dose is given one to two months after the first dose. The third dose is given six months after the first dose and four months after the second dose.

### What if a Patient Cannot Complete the Series on Schedule?

If the vaccine series is interrupted, administer the next dose when possible. It is not necessary to restart the series, even if a significant amount of time has passed. Whenever possible, the same HPV vaccine product should be used for all doses in the series.

### How Safe is HPV Vaccine?

The Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) have reviewed clinical trials and post-licensure data and consider HPV vaccines safe and effective. Both HPV vaccines have been associated with local injection-site reactions, especially pain. Syncope is more common among adolescents and young adults. To prevent injury after fainting, consider observing patients for 15 minutes after vaccination. Studies continue to monitor HPV vaccine safety. Adverse events after vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS), maintained by the FDA and CDC. To receive a VAERS reporting form, call (800) 822-7967 or report online at [www.vaers.hhs.gov](http://www.vaers.hhs.gov).

### How Effective is HPV Vaccine?

In clinical studies, HPV vaccines have been over 90 percent effective in preventing infection and precancerous lesions in women caused by high-risk HPV types 16 and 18.<sup>9</sup> Since the vaccine has been licensed, associated-HPV infections in adolescent females have decreased by 56%.<sup>10</sup> The vaccine will not prevent disease in women who already have been infected by the specific HPV types included in the vaccine. The vaccine has no value in eliminating pre-existing HPV infection or in treating HPV disease.

### Can it Prevent Genital Warts?

Yes. The quadrivalent HPV vaccine Gardasil® also offers protection against genital warts for both males and females. Efficacy is close to 90% in males and close to 100% in females in protecting against genital warts caused by HPV types 6 and 11.<sup>7</sup>

### Can it Prevent Anal and Vaginal Cancers?

Yes. In 2010, the FDA approved the HPV vaccine, Gardasil®, to help prevent anal cancer in persons 9 through 26 years. The vaccine may be up to 78% effective in preventing anal cancer associated with the vaccine-related HPV types. The quadrivalent vaccine can also help prevent vulvar and vaginal cancers due to the vaccine-related HPV types.<sup>9</sup>

### How Long Does Immunity Last?

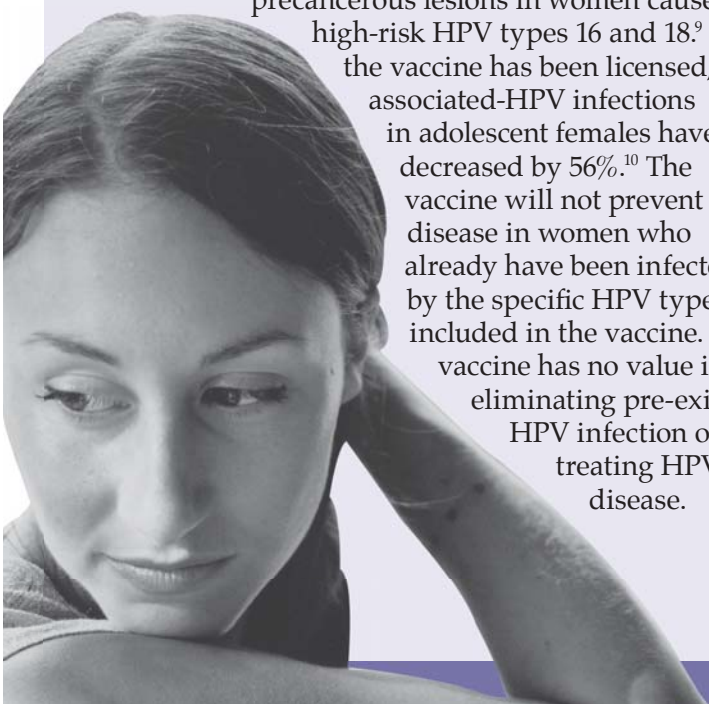
The duration of immunity is not known; current studies have demonstrated protection for at least 8 years. It is not yet known if booster doses will be needed in the future.<sup>11,12</sup>

### Who Should Get HPV Vaccine?

The federal Advisory Committee on Immunization Practices (ACIP) recommends three doses of HPV vaccine:

- » Routinely for females and males 11 or 12 years, though physicians may vaccinate starting at age 9.
- » Routinely for females 13 through 26 years and males 13 through 21 years, if not yet vaccinated or not yet completed the vaccine series.
- » For gay men, other men who have sex with men, and men with compromised immune systems who are 22 through 26 years, if not yet vaccinated or not yet completed the series.
- » Other males through age 26 years may also be vaccinated.

Patients not infected with HPV types included in the HPV vaccine benefit most from vaccination. Although HPV vaccines cannot treat prior HPV infection, sexually active patients are unlikely to have been exposed to all HPV types covered by the vaccines. Therefore, sexually active patients can still benefit from the vaccine for the virus type(s) in the vaccine they have not yet acquired.



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### **Who Should Not be Immunized with HPV Vaccine?**

Do not vaccinate individuals with a history of immediate hypersensitivity (e.g., anaphylaxis) to any component of the HPV vaccines. This includes hypersensitivity to yeast (in the quadrivalent vaccine only) and history of anaphylaxis to latex (in the bivalent vaccine pre-filled syringes only; not in single-dose vials). Defer immunization during moderate to severe illness until the illness improves.<sup>1</sup>

### **Should Pregnant Women Receive HPV Vaccine?**

HPV vaccination is not recommended during pregnancy. The vaccine has not been associated causally with adverse outcomes of pregnancy or adverse events to the developing fetus; however, data are limited. If a woman begins the vaccine series and then becomes pregnant, the series should be suspended until after the pregnancy. No treatment is recommended for women who receive one or more doses of the HPV vaccine while pregnant. Exposures to HPV vaccine during pregnancy should be reported to the manufacturer's pregnancy registry at (800) 986-8999 (Gardasil®) or (888) 452-9622 (Cervarix®) so that the vaccines can continue to be assessed for safety.

### **Is HPV Vaccine Required for Entry into Grade School or College?**

No. Regardless, providers should offer HPV vaccine during routine medical visits for children 11 or older, and urge parents to vaccinate their children according to ACIP recommendations.

### **Does the HPV Vaccine Replace Pap Screening?**

No. It is important that women continue to receive routine Pap screening. Because the HPV types targeted by the vaccine account for 70 percent of cervical cancer, the cancer risk is significantly decreased but not eliminated.<sup>6</sup>

### **Is HPV Testing Needed for Immunization?**

No. There is no role for serologic or DNA testing for the HPV virus before or after administering the HPV vaccine. Even after infection with one type of HPV, immunization can still protect against other types covered by the vaccine.

### **Are HPV Vaccines Covered by Health Plans or Other Programs?**

The Vaccines for Children (VFC) program covers both licensed HPV vaccines for eligible girls 9 through 18 years and covers the quadrivalent HPV vaccine only for eligible boys 9 through 18 years. The VFC program serves children and adolescents 18 years of age who are either uninsured, Medi-Cal eligible, Native American, or Alaska Native. Eligible children and adolescents can also get VFC vaccines through federally qualified health centers or rural health centers if their private health insurance does not cover the vaccine.

By law, most health plans must cover all ACIP-recommended vaccines. Please check with the specific health plan for more information.

### **How Can I Participate in the VFC Program?**

VFC has more than 4,000 enrolled provider sites in California. Any medical practice providing vaccinations to low-income children meeting VFC eligibility may choose to become a VFC provider. To learn more about California's VFC program, including how to become a VFC provider, visit [www.EZIZ.org](http://www.EZIZ.org) or call the VFC program office toll-free at (877) 243-8832.

### **Are There Patient Information Materials Available?**

Fact sheets on the HPV vaccine produced by CDC and CDPH can be accessed at [www.EZIZ.org](http://www.EZIZ.org). A Vaccine Information Statement is required to be given to patients, parents, or guardians before the vaccine is administered. The most up-to-date version is available at [www.cdc.gov/vaccines/pubs/vis](http://www.cdc.gov/vaccines/pubs/vis)





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## **Additional resources can be found at:**

### **California Department of Public Health**

[www.getimmunizedca.org](http://www.getimmunizedca.org)

### **Advisory Committee on Immunization Practices (ACIP)**

[www.cdc.gov/vaccines/acip/index.html](http://www.cdc.gov/vaccines/acip/index.html)

### **American Cancer Society**

[www.cancer.org](http://www.cancer.org)

### **Centers for Disease Control and Prevention, HPV Vaccine Fact Sheet**

[www.cdc.gov/std/hpv](http://www.cdc.gov/std/hpv)

### **Food and Drug Administration**

[www.fda.gov](http://www.fda.gov)

### **National Cancer Institute**

[www.cancer.gov/cancertopics/types/cervical](http://www.cancer.gov/cancertopics/types/cervical)

### **National STD/HIV Prevention Training Center**

[www.stdhivtraining.org](http://www.stdhivtraining.org)

### **Vaccine Information Statements in Multiple Languages (Immunization Action Coalition)**

[www.immunize.org/vis](http://www.immunize.org/vis)

### **Vaccines for Children (VFC) Program in California**

[www.EZIZ.org](http://www.EZIZ.org)

### **Tips and Timesavers for Talking to Parents About HPV Vaccine**

[www.cdc.gov/std/hpv](http://www.cdc.gov/std/hpv)

## **Medical Literature**

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12. GlaxoSmithKline Vaccine HPV-007 Study Group. *Sustained efficacy and immunogenicity of the human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine: Analysis of a randomised placebo-controlled trial up to 6.4 years.* Lancet Dec 2009; 374(9706):1975–1985.

